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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,392	08/01/2001	Christos Zouboulis	2757B/102	4392
2101 7590 04/01/2008 BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618				
EXAMINER LANKFORD JR, LEON B				
ART UNIT		PAPER NUMBER		
1651				
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04/01/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/920,392

Applicant(s)

ZOUBOULIS, CHRISTOS

Examiner

Leon Lankford

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9, 10, 23-25, 28-31, 34-36, 39, 40, 43, 46 and 48-72 is/are pending in the application.
- 4a) Of the above claim(s) 39, 43, 46 and 48-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 10, 23-25, 28-31, 34-36, 39, 40, 43, 46 and 48-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Applicant's arguments have been considered however a showing to overcome a prima facie case of obviousness must be clear and convincing (In re Lohr et al. 137 USPQ 548) as well as commensurate in scope with the claimed subject matter (In re Lindner 173 USPQ 356; In re Hyson, 172 USPQ 399 and In re Boesch et al., 205 USPQ 215 (CCPA 1980). Claim 1 does not serve to distinguish over the art since it only requires "features" of sebocytes and applicant's arguments are not persuasive that one wouldn't expect at least some features of the sebocytes to remain after SV40 immortalization and this would seem consistent with the Zouboulis.

Applicant has amended the claims to indicate that the cell "expresses lipids, and further characterized in that its proliferation is modifiable by an androgen and/or a retinoid." Expression of lipids is not a particularly limiting

characteristic in that lipids of some kind are ubiquitous in cells. Applicant argues that it is surprising that the immortalized sebocytes “hav(e) the differentiated characteristics of the non-immortalized cells” but it is unclear how the expression of lipids would be “unpredictable” as applicant argues. Further, it is unclear specifically why the response to androgens and retinoids would be an unpredictable result? Does the prior art or past failures indicate that it is difficult to retain this characteristic? If so, applicant should make that case.

The main question appears to be whether or not the cited references are properly applicable and combinable to render obvious the claimed invention. Applicant is directed to pages 12-13 of *KSR v Teleflex* (500 US ____ 2007) “ ... the “When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either *in the same field or a different one(emphasis added)*. If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.”

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 23-38, 40-42, 44, 45, 47 & 63-68 are rejected under 35 U.S.C.

103(a) as being unpatentable over Zouboulis et al (*Dermatology* 196) or Rosenfield (6004751) in view of Bryan (*Crit Rev Onc* 5(4)).

Zouboulis and Rosenfield teach cell cultures of sebocytes particularly taken from facial sebaceous glands. Zouboulis teaches cell culture of sebocytes dates to at least 1989. The references do not teach that the cells are immortalized, however at the time the invention was made, it would have been obvious to immortalize the sebocytes of Zouboulis and/or Rosenfield because Bryan clearly teaches that cells in culture can be immortalized by SV40 and motivates one of ordinary skill in the art to do so because of the obvious advantages for study of having a cell line which does not die off. The method is not exclusive to Bryan and has been done for decades in scores of cell types. Given the breadth and success in the art of immortalization via SV40 (and other known immortalization techniques), there was clearly a reasonable expectation of success for one of ordinary skill in the art at the time the invention was made to make an

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immortalized human sebocyte cell line. It follows that the immortalized cell line, *per se*, would have been obvious at the time the invention was made.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/
Primary Examiner, Art Unit 1651